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10/730,218

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Alessandro Luigi Spadini

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UNILEVER INTELLECTUAL PROPERTY GROUP  
700 SYLVAN AVENUE,  
BLDG C2 SOUTH  
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER

RAE, CHARLESWORTH E

ART UNIT

PAPER NUMBER

1611

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/730,218	<b>Applicant(s)</b> SPADINI ET AL.	
	<b>Examiner</b> CHARLESWORTH RAE	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9,11-16 and 18-39 is/are pending in the application.
- 4a) Of the above claim(s) 18-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 9, 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/21/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

#### DETAILED ACTION

Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114, received 2/21/08.

Applicant's claim amendment received 2/21/08 is acknowledged and made of record.

#### Information Disclosure Statement

Receipt of applicant's information disclosure statement received 2/21/08 is acknowledged.

#### Status of the Claims

Claims 1, 3-6, 9, 11-16, 18-39 are currently pending in this application.

Claims 18-39 are withdrawn for examination purposes for being directed to non-elected subject matter.

Claims 1, 3-6, 9 and 11-16 are presented for examination.

#### Response to applicant's arguments/remarks

##### Objection to claims

The rejection is withdrawn in view of the amendment of claim 1.

##### Scope of enablement rejection under 112, 1<sup>st</sup> para

Upon further consideration, this rejection is withdrawn in view of applicant's persuasive arguments.

##### Rejection under 103(a)

Applicant contends that this rejection should be withdrawn for essentially the following summarized reasons (see applicant's Response received 2/21/08 at pages 9-11):

1) Beerse et al. fails to establish a prima facie case of obviousness as it relates to an antimicrobial composition comprising a benzoic acid analog and a dermatologically acceptable carrier for the benzoic acid analog when complexed with metal wherein the composition has a pH of about 1-7 and is substantially free of a specific organic acid; this composition does not provide a composition where at least two different components of the dispersed phase can react with each other when blended with water according to instant claim 1.

2) Leyland et al. fails to establish a prima facie case of obviousness because said reference fails to teach two components dispersed in the same phase than can react with each other when dispersed or dissolved in water and where the phase is stabilized by organophilic particles.

3) Diec fails to establish a prima facie case of obviousness because it relates to microemulsion gels based on a microemulsion of the oil and water type in which droplets of the discontinuous oily phase are joined to one another by one or more crosslinking substances and where the molecules are distinguished by at least one hydrophilic region and by at least one hydrophobic region.

In response, this rejection is maintained as applicant's arguments are not found to be persuasive for the reasons previously made of record and for the following additional reason:

a) Applicant's arguments ignore the broad scope of the instant claims and are essentially directed towards non-recited limitations.

## **REJECTIONS**

### **Claim rejections – 35 USC 103(a)**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The above discussion in connection with the Response to applicant's arguments/remarks with regards to the rejection under 103(a) is incorporated by reference.

For purposes of claim rejections under 103(a), the term "*a dispersed phase including a first component, the first component being capable of chemically reacting with a second component that is different from the first,*" as recited in claims 1, is

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reasonably construed to mean the “discontinuous or external” phase of an emulsion wherein any ingredient present in the dispersed phase is reasonably construed to be the “first component” The “*first component*,” as recited in claim 1, is reasonably construed to be capable of reacting with any other component “*second component*,” that is present in the composition or external to the composition i.e. the first component may reasonably react with a second component e.g. hair or skin, at the point of use of the composition; or may be capable of reacting with a carrier in the composition or different ingredient in the composition. For purposes of this rejection, the term “organophilic particle stabilizer” as recited in claim 1, for example, given its broadest reasonable possible interpretation in light of the disclosure of the instant application, is construed to mean organophilic particle with stabilizer properties. The term “during cleansing and/or skin treatment by a user” as recited in claim 1 is construed to constitute intended use, which is not being given patentable weight as the claimed invention is directed to a composition.

The term “*substantially anhydrous carrier*,” as recited in claim 1, is reasonably construed to mean any carrier that is not 100% water. The term “*carrier*” given its broadest reasonable interpretation is construed to include any solvent, or diluent, or vehicle that is not comprised of 100% water.

The term “*first component is substantially unsolvated in the carrier*,” as recited in claim 1, is reasonably construed to mean any first component that is completely present or contained in the dispersed phase, wherein the dispersed phase is dispersed within an oil phase by means of an emulsifying agent.

The term “*an organophilic particle*,” as recited in claim 1, is reasonably construed to mean any ingredient that is present in the dispersed phase in the form of a particle i.e. not completely dissolved/solubilized in the dispersed phase, including powders, semi-solids, and colloidal particles (Steadman’s Medical Dictionary. 1995; page 1259).

Claims 1-6, 9, 11, and 13-17 are rejected as being unpatentable over Beerse et al. (US Patent 6,294, 186), in view further view of Puvvada et al. (US Patent 5,952,286) and Zhang et al. (US Patent 6,780,826).

Beerse et al. teach compositions comprising water-in-silicone emulsions having a **dispersed phase** (i.e. limitation “a” of instant claim 1) including a **first component** (salicyclic acid; limitation “a” of instant claim 1), and a **second component** (e.g. sodium chloride; limitation “a” of instant claim 1), glycerin and denatured ethanol (i.e. a water soluble **anhydrous fluid/carriers** = substantially anhydrous carrier limitation of item “b” of instant claim 1, and claim 9), and PVP is reasonable construed to be an **organophilic particle/surfactant/stabilizer** (satisfies the “organophilic particle stabilizer” limitation of claim 1; and the stabilizer limitation of claim 1; and the surfactant limitation “d” of claim 1 (col. 51, Example 16-18). It is noted that the limitation “*an anionic surfactant in a concentration of at least 2% by wt. when the at least one stabilizer consists solely of waxy particles, amphipathic compounds, or a combination thereof*,” recited as item “e” of instant claim 1, is reasonably construed to be essential only when the at least one stabilizer consists solely of waxy particles, amphipathic compounds, or a combination thereof” (col. 51, Example 16-18). The first and second

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components taught by Beerse et al. are reasonably construed to be capable of chemically reacting via non-polymerization (limitation recited in instant claim 3). The first component is construed to be “*substantially unsolvated in the anhydrous carrier*” in the presence of the PVP ( limitation “d” of instant claim 1, and limitation recited in instant claim 2) (col. 51, Example 16-18). However, Example 21-25 teach a liquid handsoap containing anionic surfactants which are reasonably construed to be substantially unsolvated by the anhydrous carrier (e.g. ammonium lauryl sulfate and ammonium laureth-3 sulfate are taught by Beerse; limitation recited in instant claim 11; see col. 53). Beerse et al. teach compositions comprising a **continuous phase** (limitation “b” of instant claim 1; see col. 51, Example 16-18), and **emulsifying agents** (e.g. aluminum starch octenyl succinate; synthetic wax; col. 51, Example 51). Beerse et al. teach composition containing additional ingredients, including pemulen and carbomer (= hydrophilic structuring polymer; see col. 51, Example 14-15); hydrogen peroxide (col. 56, Example 33-35); and petrolatum, propylene glycol, cetearth-10, cetearyl alcohol, and PEG-330 (see cols. 56-57, Example 33-35). Beerse et al. also teach powders inorganic powders (e.g. gums, chalk, Fuller’s earth, kaolin, iron oxide, mica, sercite, muscovite, phlogopie, synthetic mica, lepidolite, biotite, Lithia mica, vermiculite, magnesium carbonate, calcium carbonate, aluminum silicate, starch, smectite clays, alkyl and/or trialkyl aryl ammonium smectites, chemically modified magnesium aluminum silicate, organically modified montmorillonite clay, hydrated aluminum silicate, fumed silica, aluminum starch octenyl succinate barium silicat, calcium silicate, magnesium silicate, strontium silicate etc.), which are reasonably construed to be



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organophilic particles as these particles are reasonably construed to attract each other through nonpolar mechanisms (limitation recited in instant claims 6 and 16; see col. 41, lines 1-50; see Steadman's Medical Dictionary (27<sup>th</sup> edition.

<http://www.thomsonhc.com/pdrel/librarian/PFActionId/pdrcommon.stedmans>

.StedmansDocumentAction/DocumentDefinition/pdrcommon.Stedmans/DocumentId/28628/PFPUI/Xm1qVKg1WARh1Q/CS/186AC6); instant claim 6 also recites organophilic silica, organophilic clay. Beerse et al. teach that the **particle size** of the powders are about 0.01 to about 100 microns, which overlaps with the range of particle size recited in instant claims 4-5. Beerse et al. teach structuring agents (limitation recited in claim 12; see col. 17, lines 33-64). The formation of lamellar, hexagonal, or cubic surfactant phases upon contact with water at 25 ° C, as recited in instant claim 12, and the term "wherein the first and second components do not substantially react with water or each other until dispersed or dissolved in water at 25 ° C," are construed to be within the knowledge and skill of an artisan skilled in the art (col. 13, line 10 to col. 14, line 40; and col. 17, lines 33-64). Beerse et al. teach that emulsifiers having an HLB value outside of from about 2 to about 14 can be used in combination (col. 15, lines 7-35). Beerse et al. teach compositions comprising a carrier (i.e. the emulsion) wherein the carrier contains an oil (i.e. silicone oil = cyclomethicone), an emulsifier (e.g. cetyl palmitate, or triberhenin), and wherein the stabilizer is an organophilic clay (= hectorite); and the composition contains a total of at least about 10% of reactive dispersed solids by wt., which reasonably overlaps with the limitation of at least about 10% of reactive dispersed solids by wt. recited in instant claim 16, as the term "*at least about 10%*" as

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recited in instant claim 16, is reasonably construed to encompass amounts above 1%. (see Example 11-13, col. 50 ). Beerse et al. teach a continuous phase containing a polyorganosiloxane oil (between about 50% and 99.9% by weight of organosiloxane oil and less than about 50% by weight of a non-silicone oil, which reasonably meet the instant claimed limitation of “a substantially anhydrous carrier” as recited, for example, in instant claim 1 (column 12, lines 59-63). Beerse et al. teach that polyalkylsiloxanes useful in the composition include polyalkylsiloxanes with viscosities of from about 0.5 to about 1,000, 000 centisokes at 25 ° C; suitable non-silicone oils for the continuous silicone phase, include e.g. mineral oil, vegetable oils, synthetic oils, and semi-synthetic oils (col. 13, line 10 to col. 14, line 40). Beerse et al. teach a dispersed phase of the composition wherein the aqueous dispersed phase is a dispersion of small aqueous particles or droplets suspended in and surrounded by the continuous silicone phase; the aqueous phase can be water and one or more soluble or dispersible ingredients, including e.g. thickeners, acids, bases, salts, chelants, gums, water-soluble or dispersible alcohols and polyols, buffers, preservatives, sunscreens agents, and colorings (col. 14, lines 41-59). Instant claims 13-15 and 17 recite limitations (e.g. *first component is capable of producing a gas in aqueous solution when reacted with an acid and the second component is an acid or forms an acid in the presence of water; the first component is capable of generating a peroxide compound when dissolved in water; the first component is capable of generating sulfide ions when reacted with an alkaline material in water; the first component is a solid or semi-solid containing dissolved carbon dioxide*), which are reasonably construed to be within the skill and knowledge of

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an artisan skilled in the art. For example, Beerse et al. exemplify a composition comprising hydrogen peroxide (limitation recited in claim 14; see Example 33-35, col. 56). As stated above, Beerse et al. do not teach lamellar compositions.

Puvvada et al. teach lamellar, spherical and rod-like micelles for use in formulating cleansing compositions (col. 1, line 27 to col. 2, line 30). Puvvada et al. also teach that unexpectedly, it has been found that certain liquid fatty acids or derivatives used in a typical rod-micellar solution, can induce a lamellar phase (col. 2, lines 31-63). Puvvada et al. teach that such lamellar phase compositions are preferred because they can readily suspend particles such as emollient particles and yet readily pour out (col. 3, line 57 to col. 4, line 3). Puvvada et al. also teach compositions comprising structurants such as carbomers (e.g. Carbopol), clays, and unsaturated and/or branchend long chain (C8-C24) liquid fatty acid or ester derivatives; short chain saturated fatty acid such as capric acid or caprylic may also be employed (col. 8, lines 17-55). Puvvada et al. teach that structuring agent may be defined as having a melting point below about 25 degrees Centigrade (col. 8, lines 53-54). Instant claim 12 recites the term "further comprising structuring agents that form lamellar, hexagonal, or cubic surfactant phases upon contact with water at 25 degrees Centigrade.

Zhang et al. (6,780,826) teach methods of enhancing shine of skin comprising, for example, an oil containing rinse-off care composition comprising platelet-let particles delivered in oil-containing bar compositions or particle-in-oil liquid emulsions which unexpectedly enhance shine (col. 2, lines 57-65; and col. 3, lines ). Zhang et al. also

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teach compositions comprising particles e.g. titanium oxide coated substrate such as mica (col. 6, lines 26-64).

Based on the teaching of Zhang et al. of the enhancing shine compositions comprising organophilic particles wherein the composition also contain at least some hydrophobic benefit agent or emollient (abstract), someone of skill in the art would have been motivated to combine the teachings of the above cited references to create the instant claimed inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

Claims 1-6, 9, and 11-17 are also rejected under 103(a) as being unpatentable over Leyland (GB 2,242, 358), in view of Diec et al. (US Patent 6,607,733) and Zhang et al. (US Patent 6,780,826).

Leyland et al. teach cosmetic formulations comprising a cosmetically acceptable carrier immiscibly combined with a water-in-oil emulsion comprising an aqueous phase dispersed (limitation "a" of claim 1) within an oil phase (limitation "b" of claim 1) by means of an emulsifying agent (limitation "c" of claim 1), wherein a component (satisfies the first component limitation of claim 1) capable of interaction with an ingredient of the carrier (satisfies the second component limitation of claim 1) is incorporated within the aqueous phase of the emulsion (abstract; see page 1, line 5 to page 15, line 22; see also reference claims). Reference Example 15 teach a

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composition comprising sodium lauryl ether sulphate (limitation “e” of instant claim 1); which is a compound capable of reasonably generating sulfide ions when reacted with an alkaline material and water (limitation recited in claim 15); chlorhexidene gluconate, which is a compound reasonably capable of generating a peroxide compound (limitation recited in claim 14); formaldehyde, which is a compound reasonably capable of producing a gas in aqueous solution when reacted with an acid .e.g. citric acid (limitation recited in claim 13) and the second component is an acid or forms an acid in the presence of water (see reference claim 39). Leyland et al. teach that the emulsion may contain a single emulsifying agent or a mixture of emulsifiers (limitation “c” of claim 1; see also page 4, line 22 to page 6, line 10). Leyland et al. do not specifically teach lamellar, hexagonal, or cubic forms of surfactant phases, however.

Diec et al. (US Patent 6,607,733) teach water-in-oil (W/O) emulsions comprising substituted polysaccharide thickeners, for example, cetylhydroxyethylcellulose, can be advantageously used for physiological activity in the context of cosmetic or pharmaceutical action because of its hydrophobicity (col. 14, lines 22-33). Diec et al. teach compositions comprising 0.001-20% by weight of one or more thickeners in an O/W emulsion can pass through phase inversion by altering the temperature to produce W/O emulsions containing lamellar phases, bicontinuous phases or cubic, hexagonal or inversely hexagonal phases (limitation recited in claim 12; col. 14, lines 25 -54). The term thickeners is construed to mean a structuring agent, as recited in instant claim 12.

Zhang et al. (6,780,826) teach methods of enhancing shine of skin comprising, for example, an oil containing rinse-off care composition comprising platelet-let particles

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delivered in oil-containing bar compositions or particle-in-oil liquid emulsions which unexpectedly enhance shine (col. 2, lines 57-65; and col. 3, lines ). Zhang et al. also teach compositions comprising particles e.g. titanium oxide coated substrate such as mica (col. 6, lines 26-64).

Based on the teaching of Zhang et al. of the enhancing shine compositions comprising organophilic particles wherein the composition also contain at least some hydrophobic benefit agent or emollient (abstract), someone of skill in the art would have been motivated to combine the teachings of the above cited references to create the instant claimed inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

### **Claim rejections – 35 USC 112 – Second Paragraph**

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 5, 6, 9, 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term "and/or" which renders the claimed subject matter indefinite because the word "and" is considered to have a different meaning from the word "or." It is suggested that this specific rejection may be overcome by amending the claim to either delete the term "and/" or the term "/or."

Dependent claims 3, 4-6, 9, and 11-16 are rejected for the same reasons as these claims fail to correct the deficiency of the claim from which they depend.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

24 March 2008

/C. R./

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Examiner, Art Unit 1611

/Brian-Yong S Kwon/

Primary Examiner, Art Unit 1614